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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,451

01/23/2007

Sarman Singh

4661-0113PUS1

4154

2292 7590 05/11/2009
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EXAMINER

GRASER, JENNIFER E

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

05/11/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/584,451	Applicant(s) SINGH ET AL.	
	Examiner Jennifer E. Graser	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/16/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 22-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/14/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1, 3 and 4-21 (Species SEQ ID NO: 6) in the reply filed on 4/16/09 is acknowledged. The traversal is on the ground(s) that argue that the groups are all joined by a common special technical feature, e.g., the polypeptide. This has been fully and carefully considered but is not found persuasive because the inventions of Groups I, II and V do not contain the same or corresponding special feature as they contain products which are biologically, chemically and structurally different. The polypeptide of group I and polynucleotide of group II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. The polypeptide of group I and the antibody of group VII lack the same special technical feature for the following reasons: While the inventions of both group I and group III are polypeptides, in this instance the polypeptide of group I is a single chain molecule that functions as an enzyme, whereas the polypeptide of group VII encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group I and the antibody of group VII are structurally distinct molecules. Therefore the polypeptide and antibody lack the same or corresponding special technical feature. The methods of Groups III and IV lack the same or corresponding special technical features they are not

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capable of use together and they have different modes of operation, different functions, or different effects.

However, with respect to the polypeptides of Group I and the method of making antibodies using the polypeptide, Group II, where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply

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where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 2, and 22-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Objections

2. Claims 1, 3 and 4-21 are objected to because of the following informalities: they contain non-elected subject matter which should be removed from the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3 and 4-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites 'An isolated polypeptide, as recited in SEQ ID NO: 6"; however, SEQ ID NO: 6 recites an amino acid sequence. The claim should be amended to recite 'an isolated polypeptide consisting of the amino acid sequence set forth in SEQ ID NO: 6'.

Claim 1 is also vague and indefinite because it is unclear what it encompassed by the phrase the 'polypeptide contains one or more repeat region(s) of 39 amino acids'

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because it is unclear if these regions are in addition to SEQ ID NO: 6 or embedded somewhere within SEQ ID NO: 6. It is noted that SEQ ID NO: 6 is 155 amino acids in length. The wording of the claim makes it appear that the repeat regions are 39 amino acids in length *each* yet a review of the sequence did not reveal a repeat 39 amino acid region. The specification at page 15 under the description of Figure 5 teaches that KEIMM (SEQ ID NO: 6) is the immunodominant repeat region for the Indian strain MHOM/IN/KE16/1998. Accordingly, does the claim mean to recite that this sequence is repeated 39 times. Clarification and appropriate correction is requested.

Claim 3 is vague and indefinite because it is unclear what is encompassed by the phrase 'isolated from Indian strains of *Leishmania donovani*'. Is this any strain from India that is a *Leishmania donovani* strain? Accordingly, how does one insure the strain came from India? The specification recites that the polypeptide was isolated from MHOM/IN/KE16/1998 which is a recent clinical isolate from a 10 year old female Kala-azar patient from Muzaffarpur, Bihar, India which is not any 'Indian strain of *L.donovani*' as encompassed by the instant claim. Clarification and appropriate correction is requested.

Specification/Drawings

5. The disclosure is objected to because of the following informalities: the 'Brief Description of Drawings' is confusing.

Figures 3-9 recited numerous sequences which are depicted in the Drawings. The Brief Description of the Drawings in the specification recites various sequence identifiers which are related to the sequences recited in the Drawings; however, it is

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unclear which sequence identifier accompanies the various sequences in the Drawings.

It would be helpful to insert the appropriate sequence identifier following each sequence in the Drawings to avoid confusion.

Appropriate correction is required.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

5/5/09